



# Total Force Anthrax Vaccine Immunization Program: Controversy and Conflagration

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**Total Force Anthrax Vaccine Immunization Program:**  
**Controversy and Conflagration**

Controversy and the United States military are old playmates. As far back as the legions under George Washington, there has been the grumble of dissent associated with medical protection. Washington deemed the need to variolate his forces. He had perceived a threat from smallpox and wanted to offer his troops the utmost protection. He turned out to be right.<sup>1</sup> Washington, D.C., has perceived the threat of anthrax from any of several hostile parties. The offer of protection comes in the form of the Anthrax Vaccine Immunization Program (“AVIP”). On 18 May 1998, Secretary of Defense William S. Cohen signed the Total Force Immunization Directive to provide the Anthrax Vaccine Adsorbed (“AVA”) to all active and reserve Armed Forces members over a period of seven years. The question of whether Secretary Cohen was right is one that has yet to be answered. Indeed, it is one for which many hope there will never be an answer. That answer would come at the cost of an actual attack with anthrax. That is an answer we can live without.

The AVIP is a massive program to be enacted in three phases. Phase One involves providing initiation of the vaccination sequence to troops deployed in high threat zones such as southwest Asia and the Korean peninsula. This phase started immediately in 1998. Phase Two expanded the inception of vaccination sequence to what are termed “early deploying forces.” This is meant to include active service members as well as Reserve members that would be among the first to deploy to high threat areas in the event of conflict initiation. Initial projections placed Phase Two inception in early 2000. It is here that the greatest resistance has been found, and the slowdown of the Program has been effected. Phase Three is the delivery of vaccine to all remaining service members regardless of duty specifications. This phase was to have been started in 2003.

Even prior to the program’s inception, Secretary Cohen attached four conditions that had to be met before

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<sup>1</sup>Dep’t of Defense, *Desk Reference on Vaccines and Immunity*, November 1999  
<[http://www.anthrax.osd.mil/Site\\_Files/a...Exclinical/Desk\\_Ref\\_files/mvp-guide.htm](http://www.anthrax.osd.mil/Site_Files/a...Exclinical/Desk_Ref_files/mvp-guide.htm)>.

proceeding. First was the supplemental retesting of all stockpiled vaccine to assure potency and safety. Second was government oversight approval of the Program description for delivery of the vaccine and accompanying education of recipients. Third was the establishment of a unified system of tracking to insure accurate dispensing and follow-up of vaccinations. Fourth was an independent, non-military review of the entire Program, focusing on issues with health and medical aspects. By the middle of 1998, the Department of Defense was satisfied that all four conditions had been met and proceeded to implement AVIP. Subsequently, each of the four conditions has been challenged.

The AVIP was implemented to provide maximum protection of Armed Forces to a perceived threat of a specific bioterrorism weapon. Controversy followed with haste. A groundswell of resistance soon manifested itself throughout every portion of the Armed Forces. Soldiers were reluctant, or adamantly refusing to be injected with the vaccine. Further review of the Program uncovered controversy and resistance on logistic, moral, and legal grounds. It seemed the entire concept had been flawed from the very start.

While it had certainly been expected that inoculating 2,400,000 troops with 15 million doses of vaccine would prove to be difficult, the magnitude had indeed been underestimated. Problems with acquisition of the necessary vaccine begot problems with the distribution of the vaccine, which were followed by problems with the accurate tracking of the vaccine and recipients' sequence completion. Unanticipated resistance from both the vaccine supplier and the recipient troops delay and confounded the smooth application of the Program. The troubles were just starting.

When soldiers were ordered to accept the vaccine, there was some resistance. A shortage of background information coupled with feelings of mistrust brought to light widespread fears of human rights violation. Many service members are aware of the Nuremberg conventions and the prohibition of experimental testing on humans without consent. It is often said that a little knowledge is a dangerous thing. A little knowledge

coupled with a callous response invokes instinctual self-preservation activity. All of these factors combined to foment questions in the minds of recipients. These ideas questioned the morality of the Program. These ideas added personal justification to refusing the vaccine.

Stemming from the moral questions, and encompassing the logistic difficulties that arose, legal challenge to the Program was mounted. Cases began to be tried that revolved around the use of an experimental drug without informed consent. Other challenges attacked the vaccine as being misrepresented in its approved use. Troubles even amounted from the alleged use of force to enact the directives of the Program. The results were not what the Department of Defense had hoped for from the Program.

Legal challenge, personal resistance, poor implementation, loss of personnel, and developing health concerns plagued the Program. Certainly these challenges were as much a threat as the potential of a hostile release of the disease itself.

## **Anthrax: A Historic Epidemiology**

In the smallest of packages comes the biggest of surprises. Such is certainly the case of any bacterial infection, and exponentially so an organism as pathogenic as *Bacillus anthracis*. A scourge and plague upon mankind and his domesticated flocks stretching back to the earliest records of mass disaster, this small round single-celled threat may have been one of the original plagues of the Biblical Exodus. Indeed, as written records improve with the passage of centuries, the possibility of such historical events as outbreaks of Blackleg Plague are more closely tied to the small bug with the infamous association – anthrax. Physicians named

the disease after the Greek word for charcoal, based upon the purple-black chancres that developed with infection. Elaborate records began to emerge in Europe and the New World documenting disease in animals and humans. There are French reports dating to at least 1829, and a case of treatment by a New York doctor in 1809<sup>2</sup>.

An enemy of many names, for a long time anthrax was named simply for the obvious symptom displayed about the upper body of its victims. The large purple-black sores and open chancres gave rise to the monikers *malignante pustule*, *maladie charbonneuse*, or simply charbon, or carbuncle. Then outbreaks began to appear in the tannery industry, giving rise to the term “woolsorter’s disease.” Most curious was the sudden appearance of anthrax in the early decades of the twentieth century. These were among persons that had no contact with hide processing or agriculture, such as barbers and soldiers. These cases were subsequently traced to the shaving brushes that had been produced from contaminated horsehair.

Scientific breakthroughs began to amass beginning in 1849, with the concurrent discoveries by Aloys-Antoine Pollender, and Pierre Rayer with his disciple Casimir Davaine, of a large rod-shaped contaminant in the blood of domestic animals felled by the charbon. The basic criteria for biological proof were met when contaminated blood was injected into a healthy animal, resulting in its death from the same disease. The emerging field of microbiology seized upon this knowledge to treat such a deadly scourge. Noted German biologist Robert Koch, later awarded the 1905 Nobel Prize for Physiology or Medicine for his work with tuberculosis, succeeded in producing a pure (or reasonably so for the time) culture in 1876<sup>3</sup>. His micrographs from this culture are still used in many modern microbiology and epidemiology textbooks. His laboratory was the four-room flat he shared with his wife of the previous ten years. His tools were of his own creation, including the sharpened

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<sup>2</sup>David Hosack, M.D. “A Case of Anthrax, Successfully Treated,” C.S. van Winkle, New York (1809).

<sup>3</sup>Robert Koch, “Die Aetiologie der MilzbrandKrankheit, begrundet auf die Entwicklungsgeschichte des Bacillus Anthracis.” *Beitrage zur Biologie der Ppanzen*, Vol. 2, No. 2, pages 277-310 (1876).

wood splinters that pre-dated hypodermic needles<sup>4</sup>. His time was split between his regular medical practice and his personal quest for knowledge. His results are still cited today.

Using the work of Koch and Davaine<sup>5</sup> as a starting point, and based upon his own discoveries of vaccination with attenuated pathogens, the Great Doctor, Louis Pasteur, devised an anthrax vaccine all the way back in 1881. The production of immunologically active serum was then put to use in the treatment of woolsorter's disease outbreaks in places such as the wool mills of the northeastern United States. A report on the prevalence of anthrax in Massachusetts published in 1920<sup>6</sup> suggested that the best course of treatment "...has been rest in bed, liquid diet and bichloride poultices combined with anthrax serum." This proved to be of significantly lower mortality than surgical removal of malignant pustules from the upper body and head of victims. Indubitably, avoiding surgery also avoided a great deal of pain and scarring, especially with the surgical techniques of the day.

One of the greatest discoveries about *B. anthracis* occurred in the 1950s. Previously, mortality was thought to result from so-called "log-jam" effect of bacteria physically plugging capillaries in numbers of greater than a billion per milliliter of blood. Researchers then found that only one third of one percent, or a mere three million bacteria per milliliter, could result in death of an animal. Furthermore, the blood of a near-death anthrax infected animal could be separated to provide serum with no bacteria. This serum could subsequently induce anthrax-like symptoms in uninfected guinea pigs. An independent, diffusable toxin must be at work. However, the actual mechanism of action used by the toxin was unknown, until very recently. Research done through the National Cancer Institute, and just recently published<sup>7</sup>, has implicated anthrax Lethal Factor

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<sup>4</sup>NOBEL LECTURES, PHYSIOLOGY OR MEDICINE 1901-1921 (Elsevier Publishing Company, Amsterdam).

<sup>5</sup>LXI C. R. ACAD. SCI, OBSERVATIONS VERBALES PRÉSENTÉES À LA SUITE DE LA COMMUNICATION DE M. DAVAINÉ SUR LA MALADIE CHARBONNEUSE, 506-512 (Sept. 25, 1865).

<sup>6</sup>Stanley H. Osborn, M.D., C.P.H., "Anthrax Problem in Massachusetts" (1920).

<sup>7</sup>Nicholas S. Duesbery, et al., *Proteolytic Inactivation of MAP-Kinase-Kinase by Anthrax Lethal Factor*, 280 SCIENCE 734-737 (May 1, 1998).

in the destruction of an enzyme called MAPKK, or mitogen-activated protein kinase. This is fatal to the cells, and thus to the organism infected.

Needless to say, if the method of the enemy is a mystery, then avoidance is the best plan of action. During the earlier part of the previous century, countries enacted methods of quarantines for animal products from foreign contamination hotspots. Additionally, extensive research was put into finding a way to disinfect the materials without damaging them and making them unusable. Several methods using acid solutions were developed. In 1921<sup>8</sup>, the British government detailed an extensive decontamination system based in Liverpool. The memorandum even included floor plans and a projected budget for long range operations. However, effective avoidance was not until mass production of high quality vaccine.

Even avoidance can be futile when the danger is being manipulated by hostile entities. As the Department of Defense is fond of saying, bioterrorism weapons are real. The Cold War produced deadly research on both sides of the Iron Curtain. Sometimes, however, things went awry. In 1979, the Russian research station at Sverdlovsk experienced an accidental leak of anthrax into the neighborhood<sup>9</sup>. Different reports exist, but somewhere around 64 to 67 humans and far more numerous domestic animals died from exposure to the bacteria. Apparently, a filter had been accidentally left off of a ventilator to the facility, permitting contaminated air to be vented to the outside. The classically stern Soviet Union denied the accident for years, until *glasnost* opened the region to outside view. Subsequent analysis determined that the more than one hundred cases of anthrax had been co-located to a narrow downwind swath at the exact time of the day of the leak. Perhaps more frightening is a deliberate release of dangerous agents on an unsuspecting populace. During the recent trial of the Japanese doomsday cult, Aum Shinrikyo, it was revealed<sup>10</sup> that the

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<sup>8</sup>“Memorandum on the Disinfecting Station Established in Great Britain for Disinfection of Wool and Hair,” His Majesty’s Stationary Office (1921).

<sup>9</sup>Matthew Methelson, et. al, *The Sverdlovsk Anthrax Outbreak of 1979*, SCIENCE, 1202-1208 (November 18, 1994).

<sup>10</sup>*SOWING DEATH: A special report.; How Japan Germ Terror Alerted World*, N.Y. TIMES, May 26, 1998, at A1.



terrorists had attempted to release anthrax onto unsuspecting citizens at various sites. The trial was only for the sarin gas releases in the Tokyo subway, but revealed far more than that. Indeed, the cult tried to spread several different types of bioterrorism agents. Members had even been sent on missions to Africa to find samples of Ebola virus. There have even been attempts at bioterrorism activity inside the border of the United States. In 1998, an individual by the name of Larry Wayne Harris was arrested in Nevada<sup>11</sup> when it was believed he was carrying *B. anthracis* spores. Mr. Harris had been previously arrested in 1995 for mail fraud when he procured Bubonic Plague from a scientific facility called the American Type Culture Collection (“ATCC”). Mr. Harris had also been previously linked to the supremacist group Aryan Nation. With recent census data suggesting that whites are no longer the majority in large urban regions such as New York and San Francisco, the threat of violence by an immoral group armed with a weapon of mass destruction should indeed strike a note of fear in the heart. Fortunately, it was later revealed in this case that Mr. Harris was simply in possession of the anthrax vaccine.

From its rumored use in the Gulf War, stretching back through the mists of history to its ravages of Old World populations, anthrax has been a formidable enemy. The tiny bug with the devastating consequence has, and will, haunt us from the hands of man and nature both. Great strides have been made in the understanding of the causality. This knowledge is the key weapon in the containment, control, and continued vigilance against potential disaster.

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<sup>11</sup>T. M. Edwards, *Catching a 48-Hour Bug*, TIME, March 2, 1998.

## Anthrax: A Technical Representation

*Bacillus anthracis* is a single-celled eukaryotic organism similar in appearance to several other *Bacillus* species such as *B. cereus*, *B. subtilis*, and the butterfly larva pathogen *B. thuringiensis*. All these bugs share a cylindrical, or rod, morphology approximately five to ten microns (micrometers, or millionths of a meter) in length and about one micron in diameter. In a liquid suspension, such as they are found naturally in the blood, they form longer clumps and chains held together by sticky molecules called glycoproteins. These glycoproteins are a distinguishing characteristic of bacteria designated “Gram-positive” by the ability of the cell to be stained with a concoction of dyes known as the “Gram Stain.” *B. anthracis* has been demonstrated to have the potential to grow in the absence or presence of oxygen, technically termed a facultative anaerobe. The most remarkable, and certainly the most threatening aspect of the bacteria is the ability to form what are called endospores, or more commonly just spores. These spores are a sort of suspended animation form of the bacteria that can survive without air or water for extensive lengths of time (centuries) in extreme conditions of temperature. Because of this spore-forming ability, *B. anthracis* can hide and avoid decontamination, re-emerging when conditions are advantageous to resume a career of pestilence. There are reports of anthrax contamination still present at the Sverdlovsk site, as well as 19<sup>th</sup> century outbreaks in Europe. Anthrax spores could even be a sort of explanation for legends such as a mummy’s curse. The spores could be laying dormant on the hair and hides buried in a tomb, awakening when some foolish explorer enacts his raid. Alas, he mysteriously dies at a later date from a horrible conflagration of black boils.

*B. anthracis* causes anthrax<sup>12</sup>. Anthrax is a disease of warm-blooded vertebrates, particularly domestic

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<sup>12</sup>Koch, *supra* note 3.

grazing animals, but also wild relatives, birds, and humans. Two basic forms of the disease exist. The first, and far more common, is a cutaneous, or surface infection. Statistics about infection rates are spotty, but estimates are that somewhere around 1200 to 2000 infections occur each year globally. There have been fewer than a dozen cases in the United States in the past decade. This occurs when *B. anthracis* enters the body through a breach in the natural barrier of the skin into the vibrant tissue just beneath, such as when handling dead animals, or from natural hair shaving brushes. The spores or active Bacilli begin to grow rapidly at the site of entry. The wound quickly develops a distinctive liquidy swelling, or gelatinous edema. Within a short 12-36 hour period, this turns into a papule, or pocket of growing

bacteria that manifests as a small bump on the skin surface. As the papule fills with dying cells and fluid, it is called a vesicle, which will be dubbed a malignant pustule when it starts to ooze through the skin. The final stage of this acute infection is the development of a open sore ringed with rotting tissue, sometimes called a necrotic ulcer, or carbuncle. These are large purple-black chancres, often localized to the upper exposed regions such as the neck and arms. From here, *B. anthracis* may escape into the infected hosts bloodstream, inducing system-wide infection (septicemia) and swelling (edema). Within seven days, it is fatal. Ingested *B. anthracis* will cause a similar infection of the gastrointestinal tract. Some officials classify this as a distinct form of the disease simply because it is internal instead of on the surface skin. This is a misrepresentation. Both forms are epithelial in nature, and different from inhalation infection.

*B. anthracis* is far more dangerous when the spores are inhaled into the lungs and directly enter the bloodstream of the victim. This is a rarer type of exposure, often the result of occupational exposure as dust on infected animal hides or bioterrorism. Within hours, the victim experiences high fever and extreme chest pain, with septicemia, edema, and internal hemorrhaging quickly leading to death. Death is 99% certain in

exposed individuals without previous vaccination or antibiotic treatment.

How *B. anthracis* kills has been long researched. Initially, the relatively large size of the bacterium was thought to cause a sort of “log-jam” as they coalesced in the delicate network of blood vessels. Later, scientists determined that even a few bacteria could kill, and theorized a chemical product was at work. This was demonstrated by filtering the bacteria out of infected blood and re-injecting into healthy animals. The filtered blood could cause death. Further research determined that the *B. anthracis* produces three soluble proteins called protective antigen, edema factor, and lethal factor, or LF in the parlance of scientific alphabet soup. These proteins were shown to associate in pairs to form what were dubbed Lethal Toxin and Edema Toxin. The actual killer here is the Lethal Toxin<sup>13</sup>, which is made up of protective antigen and LF. Protective antigen was found to be in both toxins, and formed the basis of the currently available vaccine. How LF acted remained a mystery until nearly the end of the twentieth century. Based upon similarities to other known proteins, it came to be thought that LF was a metalloprotease, capable of cutting an essential protein in cells. At long last<sup>14</sup>, researchers discovered the target substrate as MAPKK. This target is a family of molecules vital for the housekeeping and maintenance of every cell in the body. Without a whole, functioning MAPKK, the cell dies. Without enough living cells, the animal dies. It is hoped that this new knowledge of the method of action will aid in the development of new treatment schemes for anthrax.

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<sup>13</sup>R.E. Lincoln & D.C. Fish, *Anthrax Toxin*, MICROBIAL TOXINS (Montie, Kadis, and Ajl, eds., Acad. Press, New York).

<sup>14</sup>See Duesbery, *supra* note 7.

## Anthrax Vaccine Adsorbed: A Technical Examination

A vaccine is a biological product designed for prophylactic protection from disease by stimulation and education of the victim's own immune system in advance of pathogenic challenge. Vaccines have been a part of western medicine for centuries, and used in primitive form for millennia. Midwives and doctors from the Middle Ages would expose patients to diseased blood or scabs to stimulate the immune response. Scientific advancement brought refinement for injectible protectants by the likes of Louis Pasteur. Pasteur demonstrated effective use of attenuated, or weakened, pathogens as a source material for personal protection from such scourges of the day as smallpox, measles, and anthrax. To reduce the chance of accidental infection with fully pathogenic material, which could be fatal, doctors learned to macerate or filter the inoculum to fragment or remove cells. This leaves behind a slurry of cellular proteins and components that can all stimulate immune responses. The advent of recombinant DNA technology allowed refinement of the inoculum by eliminating unnecessary ingredients. In these cases, a pure solution of a protein found on the surface of a dangerous bacterium or virus could be injected into a person to elicit the required immune response. Modern vaccines commonly use recombinant material to increase potency and batch consistency. Modern vaccines may also contain additives called adjuvants that enhance immune response by the body's cells. Some modern vaccination schemes may also combine multiple pathogens into a single injection. Almost all vaccinations require more than one injection over time to increase the strength of the immune response, or maintain the ability of the system to respond upon challenge – sometimes called a booster.

The Anthrax Vaccine Adsorbed that is produced by BioPort, Incorporated is a filtered, non-recombinant solution of avirulent non-encapsulated<sup>15</sup> *B. anthracis* laboratory culture. Even though a supposedly non-hazardous strain of bacterium is used, filtration removes any whole cells. This leaves behind the protein

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<sup>15</sup>Package Insert, Anthrax Vaccine Adsorbed, BioPort, Inc., Lansing, Michigan (1999).

called protective antigen, or PA. Protective antigen is a surface protein of *B. anthracis* that has been shown to stimulate an immune response in mammals. Additionally, the package insert states that the vaccine contains a certain limit of aluminum hydroxide, formaldehyde, and benzethonium chloride as preservatives. Information is lacking on the complete composition of the vaccine as it is bottled and distributed. This means that there could be far more chemicals and proteins in there than are suggested.

It is stated on the package insert that the vaccine is prepared from filtered culture medium. Although this medium, or growth solution, is called “synthetic,” it may be chock full of salts, chemicals, hormones, and other molecules that could effect reactions upon introduction into the human body. Commonly, FDA approved vaccines include on the package the complete composition of the solution, or a reference to where the entire recipe can be found. Since most proteins can be dissolved in either water or oil, it is far more common to purify the important vaccine component and provide that component suspended in pure sterile water or a lipid (fat) solution such as Lipofectin.<sup>16</sup> There are, however, reasons why this may not be done. Primarily is the difficulty in purifying the desired antigen. This is rarely true with modern tools such as High Performance Liquid Chromatography or supercritical CO<sub>2</sub> extraction. Second is the desire to produce a vaccine containing more than one distinct antigen. This stimulates the immune system to produce several types of antibody, which is often advantageous. This is, still, avoidable by careful distillation of the culture to remove unwanted components.

It is important to note that all of these methods are functional on an extremely large scale as needed to provide product to the masses. It is also important to note that producing a vaccine by mere filtration of a growth culture mandates a high degree of quality control testing. Without constant examination, the amount of antigen in any given batch of vaccine can fluctuate greatly. A low amount of antigen will result

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<sup>16</sup>Bethesda Research Laboratories, Gaithersburg, MD.

in insufficient stimulation of the immune system, effectively leaving the individual unprotected.

Aside from the confusing composition alluded to in the package insert; there are dosage instructions that call for a series of six injections over 18 months, with yearly booster injections to maintain immunity. This is a poor efficacy indicator. Vaccines such as measles and pertussis rarely require boosters, and even the most common booster given, tetanus, is reserved for every five to ten years, depending on previous inoculation records. Asking for a yearly re-immunization is akin to stating the weakness in the vaccine.

A third issue that has been raised about this particular vaccine is the effectiveness vaccination provides against different subspecies, or strains, of *B. anthracis*. Commonly, different strains (analogous to races) of a species are categorized by minute differences in the cell surface proteins, such as protective antigen. Antibodies to the protective antigen of one strain of *B. anthracis* may not confer resistance to a slightly different strain. This is of special consideration in the age of genetic manipulation of bacteria when hostile entities can create strains of bacteria never seen in nature<sup>17</sup>. However, certain portions of a protein must be consistent to insure proper function of that protein. These are called conserved regions. Antibodies to the conserved portion of protective antigen should provide immune response to all strains of *B. anthracis*.

Several of these flaws could be easily addressed by the use of recombinant DNA technology in the production of pure solutions of protective antigen. This technology was available in 1991 from researchers<sup>18</sup> at the U.S. Army research center at Fort Detrick, Maryland. This technology subsequently failed to receive adequate funding<sup>19</sup> and the program scrapped.

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<sup>17</sup>A technique of particular danger is pseudotyping, whereby a bacterium is modified so that it resembles another entirely different species or Genus but retains a large portion of its original genetic capability. Imagine a helpful bug like *E. coli* with the genes of flesh eating *S. aureus*.

<sup>18</sup>L.C. Iacono-Connors, et. al, *Protection Against Anthrax with Recombinant Virus-Expressed Protective Antigen in Experimental Animals*, 59(6) *INFECT IMMUN.*, 1961-65 (June 1991).

<sup>19</sup>Testimony of Kwai-Cheung Chan, Director Special Studies and Evaluations, Nat'l Security and Int'l Aff. Division of the Gov't Accounting Office, before Subcomm. on Nat'l Security, Veterans' Aff. and Int'l Relations, Comm. on Gov't Reform, House of Representatives (July 21, 1999).

By definition, a vaccine is designed to cause a reaction, that being the stimulation of the host immune system to be prepared for a future challenge by pathogenic antigen-bearing invaders. Concomitant with this reaction are several indications that are present to a varying degree. These may fall into the category of adverse reactions when they are generally undesirable. Examples common to nearly all vaccines are the presence of a sore and raise bump at the injection site, slight tinnitus, or ringing of the ears, and general queasiness or a feeling of slight malaise. These are the result of localized and systemic stimulation of non-specific immune system components that respond to any and all foreign challenge. These are rarely hazardous, but in a few cases escalate to anaphylactic shock, which can be fatal. This shock can be treated by the administering physician immediately and successfully.

Some vaccines produce additional reactions in some individuals. These may include extended nausea, chills and sweats, dizziness and blackouts, and longer term muscle soreness. Anthrax Vaccine Adsorbed has been implicated in all these reactions as well. Additionally, some recipients have reported excessive swelling of hands and feet, numbness, photosensitivity, auto-immune disorder, miscarriage, and fetal trisomy. BioPort itself professes not to have any data relating to the effect of the vaccine in regards to carcinogenicity, teratogenicity, or impairment of fertility. These are indeed all elements to add mistrust of the vaccine. By most standards, the BioPort Anthrax Vaccine Adsorbed is consistent with immunization products from the first half of the twentieth century, not the start of the 21<sup>st</sup> century.



## Logistical Difficulties of the AVIP

On 18 May 1998, Secretary of Defense Cohen signed the Total Force Immunization Directive to provide the Anthrax Vaccine Adsorbed (“AVA”) to all active and reserve Armed Forces members over the period of seven years, including new recruits. Simply put, this means every member of the Army, Navy, Air Force, Marines, Coast Guard, Army Reserves, Navy Reserves, and Air National Guard will receive the series of six injections of AVA, regardless of active duty, impending retirement, or new enlistment. The massive scale of this program necessitated classification of three levels of immediacy for distributing the available vaccine supply. Force members were classified into three phases relative to their imminent threat of exposure by time spent in several “hot spots” such as the Korean peninsula, or the Saudi peninsula. Immediately, concerns were raised by military members and civilian lawyers about the logistical difficulties of a program of such massive size.

It is estimated that the program will vaccinate more than 2,400,000 members of the Armed Forces by the year 2005. Simple math dictates that this is more than 15 million doses of AVA, solely for the initial immunization. This does not account for the yearly booster shots as needed. By January 2000, only about 1.4 million doses had been dispensed. At that rate, the seven-year mark would see less than half the required number of inoculations given to service members. This is far short of predictions and aspirations that the Department of Defense has put forth. This is despite the allocation of doses for immediate use in soldiers deploying or currently deployed in southwest Asia or the Middle East. As policy currently stands, these primary risk troops were to have been given at least one of the six injections prior to being deployed. Statistics on the actual percentage of deployed troops that have had their shots seems to be difficult to access. Instead,

there exist numerous cases of refusal of vaccine at domestic Reserve force bases. This suggests that the necessary doses are not going to the designated first wave of inoculees. Additionally, by deploying soldiers with only one of six in a series of shots adds to the degree of difficulty in ensuring the proper receipt of the remaining five shots. Recipients need to be carefully tracked and notified when to get each subsequent injection. By admission of the Pentagon, this has been lax.<sup>20</sup> Although statistics can be easily manipulated, the Department of Defense suggests that 70 to 90 percent of service members are given a shot within 30 days of schedule. This sounds reassuring until it is noted that the first three shots of the sequence are given at 14-day intervals, meaning that 30% of the deployed troops may be missing one or two of their shots.

The Department of Defense is attempting to track vaccine administration by use of a computerized system called “DEERS”, or Defense Enrollment Eligibility Reporting System. This collects data from the separate military branches, each of which maintains a distinct system of records. The Army uses its Medical Protection System database (“MEDPROS”). The Navy, Marines, and Coast Guard use the Shipboard Automated Medical System (“SAMS”). The Navy Reserve uses a system called “RSTARS”. The Air Force uses its Military Immunization Tracking System (“MITS”). It is errors and inefficiency in data entry that spokespeople for the AVIP invoke when suggestions of tardy and incomplete tracking arise. Great effort is being spent to update and correlate the database, but it is not enough. The tracking and timely dispensation of vaccine among a highly mobile force is inherently flawed by slow communication, human discrepancies in reporting, and tight constraints on vaccine administration timing. Of course, this would have greater impact if there were even enough vaccine to go around.

By its own admission, the Department of Defense does not have enough anthrax vaccine for all 2.4 million troops. Because of this shortfall, a slowdown<sup>21</sup> of the program was announced at the end of November 2000.

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<sup>20</sup>Testimony of Charles L. Cragin, Principal Deputy Assistant Secretary of Defense for Reserve Aff., to Subcomm. on Nat'l Security, Veterans Aff., and Int'l Relations, Comm. on Gov't Reform, U.S. House of Representatives (September 29, 1999).

<sup>21</sup>DefenseLink, December 1, 2000.

It is hoped that by delaying the administration of vaccine to its troops, the Department can receive more from the sole supplier, BioPort, Incorporated. This seems unlikely, faced with the troubles that BioPort has been having with the Food and Drug Administration, its creditors, and its own employees.

In 1990, 1991, and 1998, BioPort was awarded successive contracts<sup>22</sup> for the production of over 15 million doses of Anthrax Vaccine Adsorbed. However, the plant was closed and renovated in 1998 at the request of the FDA, who found numerous deficiencies upon inspection<sup>23</sup>. Eleven lots of vaccine were placed in quarantine to be retested for efficacy. It has since reopened, and has announced the desire to meet the contracts, but is currently in negotiations over the price per dose of the vaccine. Whether BioPort will be able to meet the demand has yet to be seen, but at the current time, insufficient doses have been supplied to the Program.

Furthermore, BioPort has had some financial difficulties come to light. In his testimony before The Subcommittee on National Security, Veterans Affairs, and International Relations of the House Committee on Government Reform given June 30, 1999, Mr. Fuad El-Hibri, President and Chief Executive Officer of BioPort, brought to light several financial woes currently being suffered by the company. He noted that vaccine costs far outweigh the agreed-upon price of the Defense contracts and that “BioPort has incurred losses at a rate that cannot be sustained in the future.” This has engendered fears of inferior vaccine production by a failing company being utilized in the Program. The Department of Defense responded by giving BioPort \$24.1 million in contractual relief, including \$18.7 million as an interest-free advance payment, and thus more than doubled BioPort’s per-dose price, from \$4.36 to \$10.64.<sup>24</sup> Despite the infusion of such massive

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<sup>22</sup>DAMD17-90-C-0159 for 700,000 doses (\$4.7M), DAMD17-91-C-1139 for 6,300,000 doses (\$33.5M), and DAMD17-98-C-8052 for 8,690,000 doses (total) (\$29.108M).

<sup>23</sup>Statement of Kathryn C. Zoon, Ph.D., Director Center For Biologics Evaluation And Research, Food And Drug Administration, before the Comm. On Armed Services, U.S. Senate (July 12, 2000).

<sup>24</sup>*Pentagon Subsidy To Anthrax Vaccine Company Raises Questions*, HARTFORD COURANT, June 17, 2000, at A11.

sums to bring the Lansing, Michigan site up to code, all vaccine from the second suite awaits FDA approval before shipping. This effectively hampers the production schedule at BioPort, affecting their ability to meet the Defense contract timeline.

To add to the troubles of the company, three former employees had filed suit seeking royalties<sup>25</sup> on vaccine sold. These employees claim to have made significant modifications to the production process while working at Michigan Biological Products, Incorporated (“MBPI”), the State-run predecessor to BioPort. This has dual repercussions, as the potential lawsuit may force greater financial hardship on a struggling company, and the revelation of modified manufacturing process invites further FDA scrutiny. Even though the lawsuit was not awarded, BioPort has still given the perception of loss of accountability and poor self-regulation.

A third powerful element of the logistics of the AVIP relates in part to the tracking and record keeping activities of the issuing branches of the Armed Forces. One of the stipulations placed upon dispensing the vaccine was an accurate and fair method of tracking long-term health effects of recipients. It was deemed important to know if people got sick from this vaccine as their lives and careers progressed, no one wanted to repeat the poor medical record keeping of those who served in the Persian Gulf War, records that often didn’t report shots received.<sup>26</sup> The Department of Defense correctly perceived the massive scope of this follow-up, and applied the use of a previously existing method designed by the FDA for reporting adverse reactions to any vaccine given by any doctor throughout the United States. This system, called Vaccine Adverse Event Reporting System (“VAERS”), involves a patient seeing a doctor after receiving vaccine and noticing a reaction. It is what is termed a passive database, placing the onus of reporting on the patients themselves and absolving the administering agency of direct tracking. It is also fraught with weaknesses,

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<sup>25</sup>LANSING STATE JOURNAL, December 5, 2000.

<sup>26</sup>SEN. COMM. ON VETERANS’ AFF., 103D CONG., 2D SESS., IS MILITARY RESEARCH HAZARDOUS TO VETERANS’ HEALTH? LESSONS SPANNING HALF A CENTURY, S. REP. NO. 103-97 (Dec. 8, 1994).

especially in a setting such as the military that thrives on regimented command and following orders. Simply put, patients are not encouraged to report adverse reactions by application of peer pressure, by withholding access to reporting materials, and by utilizing misplaced trust in superior officers. Through this system, it can be expected that adverse reactions will be severely underreported.

To summarize the logistic problem facing the Department of Defense in instituting the Anthrax Vaccine Immunization Program, there are not enough doses, doctors, or opportune moments to successfully complete the basic stages of the Program, much less the necessary follow-up maintenance program and long-term assessments. However, this being a military operation, logistics be damned.

## **Moral Troubles of the AVIP**

The world of medicine is inundated with issues of morality and ethical conduct.

Misdiagnoses, abortion rights, euthanasia, health insurance related refusal of care, untested medicines with slowly realized dangers (e.g., thalidomide), and the use of unwilling test subjects all threaten medical practitioners constantly. Basic human morality tells us that before we give any medicine to a patient, we need to obtain permission, thoroughly inform the patient, and observe and treat any undesired effects of the medicine. These tenets are mandatory for even purpose-bred rodents. These should certainly be applied to anyone willing to lay down his life in defense of our freedom.

Military service has always been known to exact a cost. The benefits of life in a free society are paid for by the potential for loss of life and the accession to comply with the orders of others. It is verifiable that

not all orders are justified. Certainly, mistakes have been made in the past with medical programs. In 1932, the Tuskegee experiments with syphilis began. During the decades following the Second World War, experiments were conducted in the United States on the effects of atomic radiation on soldiers. The war in Vietnam brought the danger of Agent Orange into focus and the ability of the Government to cover-up its errors. The dawn of the last decade of the twentieth century saw the United States embroiled in the Gulf War, where the saga of forced anthrax inoculation begins, along with the use of other agents<sup>27</sup>, specifically pyridostigmine and botulinum toxin, without prior informed consent. Is it any wonder that a certain degree of mistrust pervades any mandatory military medical program? The Nuremberg principles were specifically developed to prevent forced human subject experimentation. No member of the United States Armed Forces wants to be part of any program with echoes of Nazi human rights violations.

Many of the complaints have centered on the perceived lack of information set forth by the Department of Defense when the AVIP was instituted. Initially, only vague reassurance from the staff doctor, and “That’s an order!” directives from superior officers, were the only knowledge soldiers had of what was being done to them. Later, a small pamphlet called *What Every Service Member Should Know About the Anthrax Vaccine* was distributed with administration of the vaccine. Humans, being naturally curious, and Americans, being stubbornly independent, began to research the vaccine for themselves. This self-motivated exploration exposed many of the basic concerns that vaccine refusers have reiterated throughout the controversy. Those are fear of health damage from the vaccine, career damage from side effects of the vaccine, and a sense of a loss of free will.

The fear of collateral health damage from administration of unknown and untested agents is a basic fear

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<sup>27</sup> *Id.*

of humankind: don't eat the poison berries! Again, the mistrust aspect surfaces because the military has a history of knowingly exposing its constituents to hazardous products, all in the name of national safety. Additionally, the Reservist component of the Armed Forces now has to contend with the possibility that actions taken during military duty will greatly affect life off-duty. This was distinctly expressed by members of the Air National Guard who are also employed as commercial pilots. When reports of adverse reactions arose indicating dizziness and loss of peripheral tactile sense, these fly-boys knew that they couldn't jeopardize their civilian careers for the military. Such was a similar reaction upon hearing that civilian health insurance would not provide coverage for illness stemming from the vaccine.

To ignore the complaints of constituents is dangerous. Indeed, we know that if we put our hand in a fire, the pain tells our brain to move it out. If we ignore the messages of pain, we suffer even more. Similarly, to ignore and trivialize the misgivings of a large number of vaccine candidates can burn the whole military. This is indeed what happened with AVIP. Repeatedly, adverse reactions and fears about the Program were met with disbelief, disdain, or ridicule. That is surely a result that can only harm the Department as a whole. By labeling vaccine refusers as malingerers or troublemakers, the military disrupts their own order and trust in command.

The AVIP was designed to provide a unified front against attack by a biological weapon. Instead, it has been a weapon of its own in the fractious and morally questionable reduction of troop morale, willingness, and trust. Losing any of these components weakens the military unacceptably. With the moral paucity displayed by superior officers, the commoner vaccine recipients have chosen to express their own moral outrage by refusal of treatment. If you can't trust the government, who can you trust?

## **Legal Issues**

## Federal regulation of vaccines in the United States

The first federal action taken with regard to vaccines was in direct response to the shattering effects of smallpox on U.S. citizens. In 1813 Congress called for President James Madison “to appoint an agent to preserve the vaccine matter [i.e., smallpox vaccine] and to furnish the same to any citizen of the United States.”<sup>28</sup> Congress further empowered Madison to establish a National Vaccine Agency, and required the U.S. Post Office to carry mail up to one-half ounce containing the vaccine material at no charge.<sup>29</sup>

The first modern legislation to control the quality of pharmaceutical products was passed by Congress in 1902 and entitled the Biologics Control Act. The act created the Hygienic Laboratory of the U.S. Public Health Service to control all biological products imported, exported, or engaged in interstate commerce. Although for a period of time these functions were performed under the National Institute of Health’s Division of Biological Standards, enforcement of the Biologics Control Act is now under authority of the FDA Center for Biologics Evaluation and Research (CBER).<sup>30</sup> FDA’s stated mission in this realm is to “protect and enhance the public health through regulation of biological products including blood, vaccines, therapeutics and related drugs and devices according to statutory authorities.”<sup>31</sup>

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<sup>28</sup>Dep’t of Defense, *supra* note 1.

<sup>29</sup>*Id.*

<sup>30</sup>*See* Public Health Service Act §351, 42 U.S.C.A. §262. (West 1999).

<sup>31</sup>*See* FDA website, Center for Biologics Evaluation and Research (visited April 21, 2001) <<http://www.fda.gov/cber/>>.



## **The AVA, as currently used, requires classification as an IND under FDA standards**

Although the Department of Defense insists that the FDA has determined the anthrax vaccine as used in the Anthrax Vaccine Immunization Program is not an investigational new drug (IND), but rather an approved drug being used in accordance with its approved label, there is evidence to contradict this.<sup>32</sup>

The Department of Defense alleges that failure to specifically include inhalation exposure on the AVA label is the source of most of the confusion surrounding the anthrax vaccine. It maintains that the Department has long interpreted the label as encompassing inhalation and that such omission is easily explained due to a lack of need to distinguish between routes of exposure, i.e., spores entering the body through the skin, being breathed (such as in dust from animal hides or medical equipment), or being ingested. According to the Department of Defense, vaccinating troops headed for the Persian Gulf was done with the FDA's full knowledge.<sup>33</sup>

The Department explains the 1996 IND application filed by BioPort's predecessor Michigan Biological Products Institute as part of a research initiative to determine whether a satisfactory level of protection against anthrax could be achieved with intramuscular injections on an abbreviated shot schedule. The application included a proposed study of the effectiveness of the vaccine against inhalation exposure (using an animal model) under the investigational, two intramuscular shot schedule. It was also hoped to officially list in-

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<sup>32</sup>Dep't of Defense, *Information About the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*, (March 15, 2001) <[http://www.anthrax.osd.mil/Site\\_Files/Ed\\_products/Infopaper/Infopaper.htm](http://www.anthrax.osd.mil/Site_Files/Ed_products/Infopaper/Infopaper.htm)>.

<sup>33</sup>*Id.*

halation exposure as a label indication.<sup>34</sup> Others, including Connecticut Representative Christopher Shays, Attorney General Blumenthal, and scores of military servicemen fiercely contest this proposition.

In a press release dated March 22, 2001, Connecticut Attorney General Blumenthal noted that the sole license for the manufacturing of AVA (obtained by Michigan Biological Products Institute/ BioPort) was obtained exclusively for use in agricultural and veterinary settings as protection against cutaneous contact anthrax. It never underwent proper testing nor received approval for protection against pulmonary (airborne) anthrax, the threat the Military claims provides ample justification for its Total Force Immunization Program.<sup>35</sup> This change in the target use of the vaccine is inconsistent with its original licensing and thus qualifies AVA as an Investigational New Drug (IND) under FDA standards.<sup>36</sup> In fact, the U.S. Supreme Court has explicitly held that 21 U.S.C. § 321(p)(1) mandates new drug status for any drug not generally recognized as being safe and effective for use under the conditions prescribed, recommended or suggested in the labeling.<sup>37</sup> As an IND, the vaccine may not be administered to service members without their informed, voluntary consent. Furthermore requiring service members to be vaccinated with a biologic product unlicensed for its current use violates the Federal Food, Drug, and Cosmetic Act.

### **The addition of squalene provides further justification for classifying AVA as an IND.**

There is controversy surrounding whether or not squalene, used in vaccines to foster faster, stronger and longer protective reactions, was at some point added to the anthrax vaccine, either by BioPort or the

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<sup>34</sup>*Id.*

<sup>35</sup>PRESS RELEASE, CONN. ATT'Y GEN., Attorney General Asks Secretary Of Defense, FDA To Drop Military's Anthrax Vaccination Program, March 22, 2001.

<sup>36</sup>*See generally, What Is A New Drug Within the Meaning of § 201(p) of the Federal Drug and Cosmetic Act*, 133 A.L.R. FED. 229 (1999).

<sup>37</sup>*U.S. v. Rutherford*, 442 U.S. 544 (1979), 552-53.

Department of Defense.<sup>38</sup> The FDA has not approved its use in AVA.<sup>39</sup> The military vehemently denied the presence of squalene in the anthrax vaccine until recent FDA tests revealed squalene was found in five lots of the vaccine. The Defense Department now admits to the presence of squalene in the vaccine, but claims the amount is infinitesimally small and poses no threat to safety. Their main justification is that the amount of squalene in the vaccine cannot be harmful as this amount is smaller than that produced naturally in the body.<sup>40</sup> This reasoning, however, is flawed.

The mere fact that something is safe when eaten or applied topically does not necessarily mean that it poses no threat when loaded into a syringe. “A molecule in the body sequestered from the immune system appears as foreign to that immune system when it is finally exposed to it as a molecule from outside the self.”<sup>41</sup> The risk of immune response leading to devastating destruction of healthy tissues warrants greater investment in long-term adjuvant toxicology studies and the addition of such an agent into AVA certainly provides further justification for rendering it an IND.

## **The Department of Defense Total Force Vaccination Program, by mandating service members to receive an IND, violates federal law**

The federal statute mandating receipt of informed consent from members of the Armed Forces prior to the administration of investigational drugs (which arguably include the anthrax vaccine) is entitled “Notice of

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<sup>38</sup> *Additive Found in Anthrax Vaccine*, HARTFORD COURANT, Sept. 28, 2000.

<sup>39</sup> *Additive Found in Anthrax Vaccine Questioned; Two Congressmen Initiate Probe at Hearing*, HARTFORD COURANT, OCT. 4, 2000.

<sup>40</sup> Dept. of Defense, *Information About the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*, (March 15, 2001) <[http://www.anthrax.osd.mil/Site\\_Files/Ed\\_products/Infopaper/Infopaper.htm](http://www.anthrax.osd.mil/Site_Files/Ed_products/Infopaper/Infopaper.htm)>.

<sup>41</sup> Pamela B. Asa, “Rebuttal Letter Concerning Disinformation Surrounding Her Work ‘Antibodies to Squalene in Gulf War Syndrome’” <[http://www.enter.net/~jfsorg/OfficialDocuments\\_files/DrAsa.htm](http://www.enter.net/~jfsorg/OfficialDocuments_files/DrAsa.htm)>; Pamela B. Asa, et. al., *Antibodies to Squalene in Gulf War Syndrome*, 68 EXPERIMENTAL AND MOLECULAR PATHOLOGY 58-64 (February 2000).

Use of an Investigational New Drug or a Drug Unapproved for its Applied Use.” Codified in 10 U.S.C. §1107 (1999), the statute requires the Secretary of Defense to provide any member of the Armed Forces who is to receive an investigational new drug or a drug unapproved for its applied use with written notification that the drug being administered is an investigational new drug or a drug unapproved for its applied use, the reason(s) why such drug is being administered, and information regarding the possible side effects of the drug, including any known side effects possible as a result of the drug’s interaction with other drugs or treatments. Such information must be given to the service member prior to the drug’s initial administration. Only the President is empowered to waive the informed consent requirement imposed under 505(i)(4) of the Federal Food, Drug and Cosmetic Act<sup>42</sup> for members of the Armed Forces receiving such drugs in connection with their participation in a particular military operation.

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<sup>42</sup>21 U.S.C. 355(i)(4).

Then-President Clinton considered the subject important enough to warrant the issuance of an Executive Order on September 30, 1999. Executive Order 13139, “Improving Health Protection of Military Personnel Participating in Particular Military Operations,” requires the Department of Defense to obtain informed consent from any member of the Armed Forces prior to administering him an investigational drug. Waivers of informed consent are only issued in extreme circumstances and at the President’s sole discretion in accordance with 10 U.S.C. 1107(f). The President may only grant such a waiver upon determining that obtaining informed consent is either an impossibility, contrary to the best interests of the recipient, or counter to national security interests.<sup>43</sup> The President has issued no such waivers to date.<sup>44</sup>

Air Force Instruction 40-403, “Clinical Investigations in Medical Research Guidance and Procedures” (May 19, 1994) similarly calls for Air Force give their written informed consent prior to receiving any INDs. The instruction further state that usage of any FDA approved drug in a manner other than that provided for in FDA approved indications is to be considered an “investigational use.”

Voluntary and informed consent is a crucial element of any human experimentation. The Nuremberg Code requires that experimental subjects have sufficient knowledge and comprehension of the elements involved, including the nature, duration and purpose of the experiment, to be able to make an enlightened and voluntary decision.<sup>45</sup> The principles of the Nuremberg Code prohibit the Department of Defense from conducting large-scale investigations on members of the Armed Services.<sup>46</sup> The Declaration of Helsinki<sup>47</sup> and the Common Rule of the U.S. Government<sup>48</sup> call for similar measures.

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<sup>43</sup> See 21 C.F.R. §§ 50, 312 (1999).

<sup>44</sup> *The Anthrax Vaccine Immunization Program - What Have We Learned?: Hearings Before the Comm. on Gov’t Reform*, October 3, 2000 (Statement of John J. Michels, Jr.).

<sup>45</sup> *The Nuremberg Code, Trials of War Criminals before the Nuremberg Military Tribunals*, U.S. GOV’T PRINTING OFF., Washington D.C. (1948).

<sup>46</sup> 50 U.S.C. §1520(a) (1999).

<sup>47</sup> T. A. Mappes & J. S. Zembaty, Declaration of Helsinki, World Medical Assoc., BIOMEDICAL ETHICS 211-13 (3<sup>rd</sup> Ed., McGraw-Hill, Inc., 1991).

<sup>48</sup> Federal Policy for the Protection of Human Subjects, 56 Federal Register 28,002 – 28,032 (June 18, 1991). (The Common Rule calls proscribes the use of federal funds for research involving human experimentation, unless the subject gives his informed

Under the Food, Drug and Cosmetics Act, all medical products require approval by the Food and Drug Administration prior to being sold and distributed in the U.S. or given to U.S. troops stationed in foreign countries. Under current law, an unapproved or investigational drug or vaccine can only be administered by the Department of Defense in accordance with official Investigational New Drug (IND) protocol.<sup>49</sup> Official IND procedure requires voluntary, informed consent and carefully controlled conditions allowing for evaluation of safety and efficacy.

## Side Effects

Dr. Frank Fisher, a lieutenant colonel at the Brooks Air Force Base in San Antonio, described his experience as something out of the X-files. While waiting in a line of fellow servicemen for a typhoid vaccination in 1993, Dr. Fisher received an unidentified shot that was not recorded in his immunization records. Seven years later, he's experiencing a spectrum of medical problems of unknown cause, problems so severe they forced him to leave the Armed Forces.<sup>50</sup>

Dr. Fisher is not alone. Since the Total Force Vaccination program commenced in 1998, over two million doses of the anthrax vaccine have been dispensed to over 502,000 members of the Armed Forces.<sup>51</sup> These inoculations have resulted in over 1,530 federal complaints of adverse reactions of varying severity.<sup>52</sup> Due to the controversy over the anthrax vaccine, many service members have refused to take it, even though such action usually means expulsion from the active arms services. According to the General Accounting Office, to date, twenty-five percent of pilots and aircrew serving in the National Guard and the military air reserve

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consent in advance).

<sup>49</sup>55 Federal Register 52,814 – 52,817 (December 21, 1990).

<sup>50</sup>*Doctors vs. Anthrax Vaccine*, HARTFORD COURANT, May 14, 2001, at A1.

<sup>51</sup>Dep't of Defense, *supra* note 32.

<sup>52</sup>*Doctors vs. Anthrax Vaccine*, *supra* note 50.

units have been lost due to the anthrax controversy.<sup>53</sup>

In a memorandum from Major Sonnie Bates responding to court-martial proceedings initiated against him, Major Bates questions the soundness of his Aerospace Medical Squadron Commander's assertion that Dover Air Force Base has a "normal healthy population." Major Bates cited numerous examples of ill members of Ninth Airlift Squadron:

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<sup>53</sup> *Id.*

“Michelle P. suffered from thyroid damage, an autoimmune disorder, chronic fatigue, and dizziness. She had been grounded for several months. Bill L. has also been grounded for several months. After the vaccine, he developed cysts on numerous places on the inside and outside of his body, to include his heart. He has undergone surgery to remove some of the cysts and was hooked up to an IV for six weeks. He became incapacitated at the controls of the airplane due to this illness. He was on a basic crew, so the other pilot basically flew the airplane solo to Germany. Jean T. suffers from a widespread rash over most of her body since receiving the vaccine. Jim G. suffers from severe chronic joint pain, thyroid damage, and has an autoimmune disorder. Both of his arms are in braces due to the severe joint pain. John S. has an autoimmune disorder. Jay M. has been grounded for several months. He has been suffering from crippling bone/joint pain, ringing in the ears, and memory lapses. He has been battling various infections continuously during these past several months and has developed 27 new allergies in the past few months. Dave H. experienced diverse symptoms, which included chronic bone/joint pain, chronic fatigue, and a loss of ability to concentrate. He has been cross-trained into another, less demanding career field. Mike M. had been grounded for eight months after receiving the vaccine. He has experienced eight seizures. Other symptoms include crippling bone/joint pain, memory lapses, ringing in the ears, dizziness, and an inability to concentrate. Ted D. suffered recurring infections after the vaccine and sustained thyroid damage and acute short-term memory loss. Jerry K. became chronically ill and was grounded during his last months of service before retirement. Brian B. suffers from severe bone and joint pain. Recent bone scans reveal lesions on his spin, pelvis, and ribs. Jim R. experienced chronic bone/joint pain. He said his arms frequently go numb. He has been grounded for so long the medical group has questioned him about a medical discharge. However, he is not interested in a medical discharge because he has been in the military for over 17 years and <sup>31</sup>does not want to lose his pension. Nathan P., after receiving the vaccine, has suffered from lesions in his throat and X-rays have revealed spots on his lungs. Cindy C. started experiencing episodes of vertigo, ringing of the ears, and memory lapses. She has had five vertigo episodes, described as being so severe that



Severe adverse responses were not limited to the Ninth Squadron.

“Christy M., an airman from Kirtland AFB suffers from blisters all over her body after taking the vaccine. She was told it was from her laundry detergent and was ordered to continue the series. Her condition worsened and she was sent to Wilford Hall, TX. While there she was told she may have had a reaction to the vaccine, but was still ordered to continue the series. The doctors gave her yet another dose and her condition worsened. She is afraid. She doesn’t want to take any more shots of this vaccine, but has been told she must continue.

Jeanette L., an NCO at Beale AFB has been suffering from chronic fatigue, heart dysfunctions, cysts, and other infections since taking the vaccine. She says she feels as though she is literally dying, while the clinic tells her she must continue the series of vaccines.

Kevin R., a service member in the navy has been in a coma since taking the vaccine in December. He is at Walter Reed.

Kevin E., an Army specialist fell ill in Korea after receiving the shot. His body was covered with blisters and bleeding sores. The Army had to treat him like a burn victim. He was 28 years old at the time. This service member believes it was caused by the anthrax vaccine.

Joseph Jones, A 22 year old soldier from Ft. Benning received his first anthrax inoculation on 3/17/98 and began suffering flu-like symptoms, severe headaches, a rash over arms, back, and chest, and bloody diarrhea which lasted a few days. Injection number two came 3/31/98, he began suffering the same type symptoms, only worse, when he went to the medical facility he was put on antibiotics. Then came shot number three 4/14/98 while still on antibiotics! All of this young man's inoculations came from Lot FAV020 (the expired lot). Joseph Jones' mother, has described his blackouts as seizures with muscles tightening and his eyes glazing over. Senator Phil Graham has begun an investigation of his case, and the case number is #81103787. Epilepsy has been ruled out.

Mike K., an Army specialist stationed in Germany has been sick for months with flu like symptoms after taking the vaccine. He also suffers from memory loss, blurred vision, and diarrhea. No VAERS was filed. He believes the vaccine has caused the illness. He has not been diagnosed and no tests had been conducted on him at the time of his report. He wanted help, but felt like no one was listening to him at the clinic. He did not want to take another shot, but was told he had to.

Aubrey L., has suffered from Chronic Fatigue Syndrome since 1974, when he was given an experimental dose of anthrax vaccine while stationed at Guam AFB. He nearly died. Later he was tested and shown to have been exposed to anthrax. He testified under oath before Congress in 1996.

1Lt Mike H., started his Air Force career at Charleston AFB while awaiting his JSUPT class start date at Vance AFB. While at Charleston, he started the anthrax vaccine series. He then went to Vance AFB to start pilot training. He was told he had to continue the shots since he started them. He graduated pilot training in January 2000, but is in the process of being discharged for medical reasons for symptoms he believes was caused by the anthrax vaccine.

A Wisconsin ANG member reportedly died from heart failure 11 hours after receiving the anthrax vaccine in Saudi Arabia.

Lou D., Marine Corporal at Camp Pendleton. His mother was called to his side last 4th of July with the expectation he wouldn't survive. He was previously healthy, took 4th shot in April 99, proceeded to lose 17% of his body weight, then lapsed into a week long coma. After recovering, he was told all his medical records were missing and he'd have to start all his shots over again, including the anthrax shot.

Kaliff T., an Army member stationed at Ft Carson took the anthrax vaccine this past September, went out almost immediately to play football, went home complaining of headaches and couldn't sleep. He was transported via helicopter to Denver University hospital where he experienced complete organ failure and lapsed into drug-induced coma for 2 weeks and went from 250 to 190 lbs. Army claims condition not related to the shot.

Peter M., 51, Kansas ANG at McConnell AFB. Experiencing temporary paralysis after being told the anthrax shot would not be a problem just because he had polio as a child. Being sent to Medical Evaluation Board for elimination from service.

Sgt. Bill P., Kansas ANG, former weightlifter, diagnosed first with pneumonia, then mono, then parvo, then Lyme disease, and finally Lupus after receiving the anthrax vaccine.”<sup>55</sup>

**Surely such severe side effects provide ample justification for questioning the soundness of the AVIP and the vaccine itself.**

## **.Dealing with Resistance**

The military clearly considers vaccination refusal to be a discipline issue. The Department of Defense does not, however, have a military-wide policy for dealing with service members who refuse the vaccine, and thus, in the eyes of the military, a lawful order. Instead, local military commanders are instructed to apply the principles in the Uniform Code of Military Justice (U.C.M.J.)<sup>56</sup> and guidance provided in the Manual for Courts-Martial and Service Regulations.

Although certain airforce bases have posted outlines detailing the possible repercussions from refusing to be vaccinated with AVA, the outlines tend to be vague. At Pope Air Force Base, North Carolina, a posting states that failures to obtain required immunizations are handled by the member’s commander. The commander has a full range of options to deal with the situation, from taking no action to taking punitive action under the UCMJ.<sup>57</sup> Furthermore, both active and reserve members refusing to take required vaccinations are subject to discharge.<sup>58</sup> Waivers are granted on an extremely limited basis and are restricted to certain medical conditions, including hypersensitivity to vaccines and pregnancy, and “legitimate religious objection

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<sup>56</sup>The U.C.M.J. is a federal law forming the basis of the military justice system. It states what qualifies as criminal conduct, establishes the various types of military courts, and sets forth procedures to be followed in the administration of military justice.

<sup>57</sup>“Anthrax Immunizations,” <<http://www.dallasnw.quik.com/cyberella/Anthrax/Notice.html>> (visited April 20, 2001).

<sup>58</sup>*Id.*

to immunization.”<sup>59</sup>

Action under UCMJ article 90, “Willfully Disobeying a Superior Commissioned Officer,”<sup>60</sup> is appropriate where the refused order was given by the member’s commanding officer.<sup>61</sup> When a service member is charged with willful disobedience of a lawful order, the order is presumed to be lawful unless patently illegal.<sup>62</sup> Challenging the lawfulness of an order is an issue of law to be determined by a military judge as an interlocutory matter.<sup>63</sup> Decisions by the Court of Military Appeals are given great deference as it was Congress’ intent to create a military justice system of integrated military courts with sufficient familiarity with military problems to handle these specialized issues in uniform fashion.<sup>64</sup>

Service members refusing the vaccine are finding themselves “prosecuted alongside drug users, thieves and rapists.”<sup>65</sup> The punishment dealt for refusing the vaccine has been severe: five marines enlisted at Twenty Nine Palms, California, received bad-conduct discharges; an airman in Texas was sentenced to 21 days in the brig, had his pay docked \$ 500, and was discharged from the Air Force; and five members of the Ohio National Guard were discharged over the issue.<sup>66</sup>

In Camp Pendleton, California, Marine Lance Corporal Matthew D. Perry was charged with violating an order to take the AVA series.<sup>67</sup> Corporal Perry was denied the opportunity to introduce evidence at trial concerning the safety and efficacy of the vaccine on the grounds that Secretary of the Naval Instruction 6230.4 (stating that AVA is an FDA-licensed product) precluded this inquiry and thus informed consent

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<sup>59</sup>Dep’t of Defense Directive 1300.17, *Accommodation of Religious Practices Within the Military Svcs* (June 18, 1985).

<sup>60</sup>10 U.S.C. § 890.

<sup>61</sup>U.S. v. Felix, CMA 1994, 40 M.J. 356, cert denied 115 S. Ct. 906.

<sup>62</sup>MANUAL FOR COURTS MARTIAL, Part IV, Para. 14c(2)(a)(i) (1998).

<sup>63</sup>U.C.M.J. Art. 51(b) (1988).

<sup>64</sup>See *Schlesinger v. Councilman*, 420 US 738, 758 (1975).

<sup>65</sup>*Anthrax Shots Bad Medicine? Vaccine’s Possible Perils Listed in Military Papers*, SAN DIEGO UNION TRIBUNE, June 29, 1999 (quoting Lance Corporal Jared Schwartz, of Henderson, Kentucky, court-martialed and sentenced to a bad conduct discharge and forty-five days in the brig).

<sup>66</sup>*An Airman’s Vaccination Becomes Test of Loyalty*, THE CHRISTIAN SCIENCE MONITOR, February 2, 2000.

<sup>67</sup>See *Perry v. Wesely*, 2000 WL 1775249 (N.M. Ct. Crim. App.) (2000).

is not required for its administration.<sup>68</sup> Accordingly, anthrax immunization is therefore mandatory and service members who refuse are subject to military discipline.<sup>69</sup> The U.S. Navy Marine Corps Court of Criminal Appeals denied his petition for a writ of mandamus on November 29, 2000. An appeal to the U.S. Supreme Court on the grounds that prosecution for refusing the vaccine was a violation of Corporal Perry's constitutional rights of access to the legal system and jury trial was rejected on March 19, 2001, without comment.

The Supreme Court's decision to deny cert in Colonel Perry's case is not, however, surprising. The Court has repeatedly declared that constitutional rights adverse to military interests are subject to greater limitations than in a civilian context.<sup>70</sup> Indeed, the Court has gone so far as to state that provided a regulation can reasonably be interpreted to be "relevant and necessary to the national defense" or otherwise promotes a valid government interest, it will survive constitutional attack.<sup>71</sup> The military prevails when there is any reasonable basis for the action taken. Not all service members, however, consider the AVIP program to be a reasonable action.

There's a difference between being willing to give your life and sacrificing your health over a mismanaged government contract.<sup>72</sup> Air Force Major Sonnie Bates refused the anthrax vaccine at Dover Air Force Base, Delaware, in November 1999. He is the highest-ranking active-duty military officer to turn down the vaccine. Rather than face court-martial, he chose to end his fourteen year career with the armed services in March 2000 and accepted a general discharge under honorable conditions in addition to a fine.<sup>73</sup>

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<sup>68</sup> *Id.*

<sup>69</sup> See also *Ponder v. Stone*, 54 M.J. 613 (2000).

<sup>70</sup> See *Brown v. Glass*, 444 U.S. 348, 354 (1986); see also *Parker v. Levy* 417 U.S. 733, 759 (1974).

<sup>71</sup> *Mack v. Rumsfeld*, 609 F. Supp. 1561, 1567 (W.D.N.Y. 1985).

<sup>72</sup> *Air Force Major Sonnie Bates, Court Martial In Anthrax Clash*, CBS News, Los Angeles, Oct.4,2000 <<http://www.cbsnews.com/now/story/0,1597,149811-412,00.html>>

<sup>73</sup> *Air Force Doctor, Former Pilot Sue to Have Anthrax Vaccine Declared Experimental*, STARS AND STRIPES, May 4, 2001.

U.S. Air Force physician Captain John Buck faces court-martial proceedings at Keesler Air Force Base, Mississippi, for refusing the military's controversial anthrax vaccination. He is the first physician to refuse to take the anthrax vaccine. He remains willing to be deployed in areas where anthrax is a potential concern and even offered the military complete indemnification from liability should he contract the disease, in addition to waiving his rights to a \$200,000 life insurance policy.<sup>74</sup> He was told these were not options, however, that he was still required to take the vaccine.

On May 2, 2001, Major Bates and Captain Buck filed suit in the U.S. District Court for the District of Columbia against the Defense Department and several other agencies seeking to have the AVA officially declared an IND.<sup>75</sup> The lawsuit, the first to target the FDA's role in the AVIP, maintains that such classification is mandated by the FDA's failure to authorize the vaccine for use as protection against biological warfare and cites the numerous health violations and safety concerns relating to AVIP.

## Ramifications of Continuing AVIP

Legislation has been proposed to immediately halt the Anthrax Vaccine Immunization Program of the Department of Defense. Across the country, service members and their families are anxiously awaiting the decision. It is not enough that they have been given some breathing room by the Program slow-down resulting from insufficient vaccine delivery by BioPort. There is a perceived need for a full cessation of the inoculations. However, there is a strong possibility that the Program will proceed. If this should happen, there are several ramifications that can be expected.

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<sup>74</sup>*Doctors v. Anthrax Vaccine*, supra note 50.

<sup>75</sup>*Lawsuit on Anthrax Vaccinations Targets FDA Role*, WASH. POST, May 3, 2001, at A22.

The first result of resumption of the vaccination Program is one that has been stated repeatedly in Congressional testimony by service members among the various Branches. There will be an increase in resignations and optioned retirements to avoid the vaccination requirement. The greatest affect will be in Reserve Corps, more of who have the option to leave service than in the full-time Forces. These men and women will assess the risks versus their military careers and easily see a long-range benefit to retirement. It would do none of them well to accept the vaccine only to find that in a short time, they have become sick, untreatable by civilian insurance, and unfit for civilian or military responsibilities. Among the full-time Forces, there will be a continued presence of vaccine refusers who will face Military Judicial Action, culminating in expulsion from the service. While these men and women will preserve some of their health, they will be stigmatized by the legal action against them. This will follow them through life much as a civilian criminal record would follow them, affecting future career and lifestyle opportunities. Regardless of which Corps loses the member, Reserve or Active, the net result will be a diminished troop readiness. This may be compounded further by reluctance of new recruits to join the Forces based upon fear of the vaccination Program. Fewer troops necessarily means a weaker National Defense.

Even if all the potential refusers and all prospective recruits can be assuaged in their fears of the vaccine, the Program is left with the problems of the vaccine itself. Insufficient protection is afforded by improper administration of a weak vaccine. If the supply is sufficiently bolstered to allow for Total Force Immunization as delineated by the Program, the question of the vaccine efficacy will remain. Technical analysis has shown that the vaccine is of poor quality, requiring numerous bolstering steps and excessively frequent re-immunization. The possibility of incomplete protection and misplaced faith in a weak vaccine will leave the Forces open to severe decimation in the event of an actual attack with anthrax. This again means a weaker National Defense.



Also for consideration is the long-term cost for collateral damage caused by the vaccine. As the Government has seen from its use of Agent Orange, decades after deployment serious and severe health issues can arise. Precedent has been shown to hold the Government liable for incurred medical costs. With the rising numbers of service members, this potential cost rises exponentially. It may be penny-wise but pound-foolish to implement AVIP at the current time without knowledge of the long-term associated effects of this particular vaccine. The vaccine costs about \$10 a dose, or less than \$100 for a typical four-year tour of duty. This is inconsequential to the potential of millions of dollars as reparations that might be paid in class-action lawsuits. Even in human costs, estimates suggest that it is unlikely that anthrax attack would destroy the entire Force structure, but by mandating complete compliance across the Force, there is the potential for far more people to be affected by the vaccine.

The cost of the Anthrax Vaccine Immunization Program will be higher than the projected \$200 million of the actual shots. There will be a cost in manpower, readiness, and liability dollars. As the Department of Defense is fond of saying, they are in the business of “Recruitment, Retention, Readiness, and Morale.”<sup>76</sup> Certainly these tenets are at odds with the continued deployment of the anthrax vaccine.

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<sup>76</sup>Statement of Charles L. Cragin, Principal Deputy Assistant Secretary of Defense for Reserve Affairs.